# Knowledge Acquisition Session Report
# NCI – DCP Protocol Information Office

**KA Session Date:** August 8, 2000 **Session Time:** 1:00-4:00 PM

**Session Topic:** DCP Information Needs

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**Organization:** Protocol Information Office, NCI Division of Cancer Prevention

**Session Location:** Office of Informatics conference room, Rockville, Maryland

**Type of Session:**

X____ Interview _____ Task Analysis _____ Scenario Analysis
____ Concept Analysis _____ Observation _____ Structured Interview
_____ Other:

**Documentation:** KA Report

## General Topic Area

Cancer prevention protocol abstraction elements

## Session Objective

To complete the abstraction elements model for PIMS, version 1.0

## Report Summary

The PIO (Protocol Information Office) staff invited domain experts to provide fresh insight into protocol abstraction elements. The meeting participants revised the model of protocol abstraction elements. PIMS (Protocol Information Management System) developers will use the model for version 1.0. Users of PIMS will evaluate the effectiveness of the abstraction elements and will make suggestions for improvement.

## Protocol Abstraction Model

Figure 1 shows the revised Protocol Abstraction Model. Domain experts and developers created it during the Knowledge Acquisition (KA) session, and refined it further after the KA session.

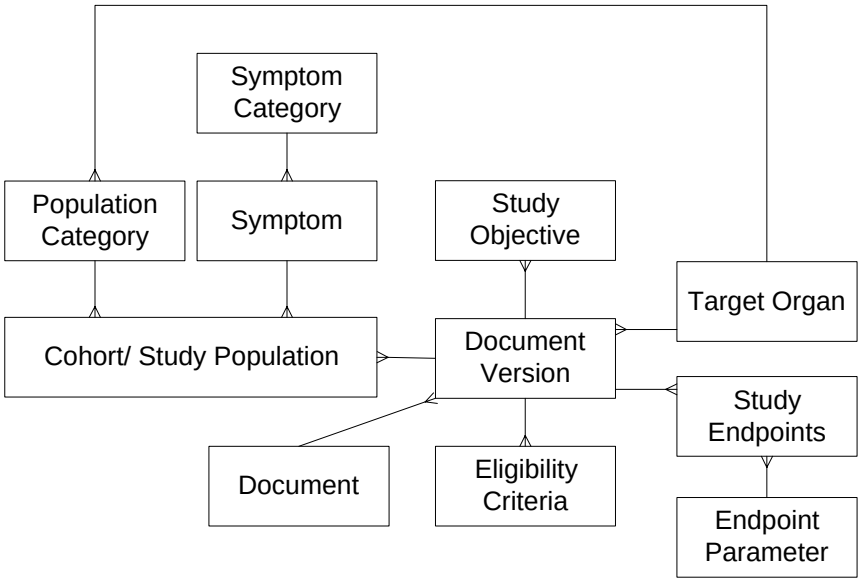


**Figure 1: Revised Model of Protocol Abstraction Elements**

The lines in Figure 1 show one-to-many relationships between the elements as they might exist in a database. When applied to the task of protocol abstraction, some elements can still be related to other elements even if these lines do not connect them. The PIO staff will look to some protocol elements to help define other ones. PIMS will draw the data from the elements as shown in Figure 1.

## Protocol Abstraction Elements

The PIO staff is still considering the abstraction element "Disease", and will decide whether to include it in PIMS, version 1.0. Some domain experts observed that the Disease is already included in other elements such as the study endpoint or the study objective. Further KA is needed to determine whether Disease as an abstraction element is required for Community Oncology and Prevention Trials Research Group (CCOP) studies.

### Population Category

Population Categories were called Risk Factors in earlier versions of the model. Since Cohort/Study Population draws some of its data from this element (see Figure 1), the PIO staff decided that it needed to include more than just risk factors.

PIO personnel will provide developers with a list of specific risk factors for inclusion in this element. PIO may provide other lists of categories, but at this time that is undetermined.

Population Categories will also include the following fields:

- Type
  - Genetic
  - Environmental
  - Family History
  - Pathologic

    - Age
    - Behavior
    - Exposure
- Target Organ
- Description

**Symptom**

In the database, Cohort/Study Population will draw data from the Symptom table. Although not directly joined in the model, symptoms are related to other abstraction elements. For example, if a study's objective were to reduce the effects of actinic keratosis (rough, red, or brown scaly patches on the skin), it would include patients with the condition in its patient population. In this way, the element of Symptom is related to (but not joined with) the element of Eligibility Criteria.

**Symptom Category**

PIO personnel will provide PIMS developers with a list of symptom categories derived from the Common Toxicity Criteria (CTC).

**Cohort/ Study Population**

Meeting participants decided to use the term "cohort" to describe the population to be included in a study. The group used "cohort" as defined in the Webster's College Dictionary (Random House, 1999, 2nd Ed.) as "a group of persons sharing a particular statistical or demographic characteristic".

The DCP Organ System Research Groups (OSRG) sometimes use pre-defined cohorts. Developers will include the pre-defined cohorts in PIMS, version 1.0. Users of PIMS will be able to select the appropriate cohort from a list. Users of PIMS will also be able to add cohorts that are not on the list.

For Phase II protocols, PIO personnel may abstract cohort information from the protocol title. Some diseases provide easily defined cohorts. For example, research has established a link between familial adenomatous polyposis (FAP) and a specific gene mutation. A cohort for a study focusing on FAP might include patients with the gene mutation.

Cohorts may be divided by using stratification factors such as:

- Age
- Gender
- Minority Status
- Whether the patient has, or does not have a certain condition (and the degree of that condition)
- Study Site

**Document**

A document is the protocol, proposal, or concept that was received by the PIO for processing within DCP. Some parts of the document can change, but the PIO wants to examine the changes in relation to the original document.

**Document Version**

Document Version refers to any revisions or amendments to a document. Study designers may change aspects of a DCP protocol, proposal, or concept after they have been submitted or approved. PIMS will allow the PIO staff to track these changes.

**Study Objective**

The purpose of the study is called the study objective. The goals may include relief of a symptom, tool validation, or prevention of a disease. Even though these are the goals identified by domain experts, there may be other ways to categorize them.

**Study Endpoints**

Study Endpoints are used to determine success or failure in a study. They are more specific and measurable than study objectives. There are two types of endpoints:

1. Primary
2. Secondary

The Primary Endpoint is used to determine success or failure with regard to the main purpose of the study. Secondary Endpoints are used to evaluate other topics of interest to investigators. Secondary Endpoint results may be used to form hypotheses for future studies.

DCP studies have a single primary endpoint. DCP studies may also have multiple secondary endpoints (in no hierarchical order).

**Endpoint Parameter**

Endpoint Parameters specify how the endpoint will be measured. The parameters can be biomarkers (e.g. biologically manifested, such as a test result), efficacy (i.e. how well did an intervention, agent, etc. work), or other.

The category titled "other" will allow Protocol Information Office (PIO) personnel to enter endpoints not included in the version 1.0 list. PIMS developers may include additional risk factors in later versions of PIMS.

**Eligibility Criteria**

These are the criteria that a patient must meet in order to be enrolled in a clinical study. Eligibility criteria can include such things as family history, previous illness or treatment, and test results within certain parameters.

**Target Organ**

The target organ is the tissue area or organ on which the study will focus. Prevention trials have one target organ per study. For example, the Primary Endpoint might specify a certain indicator for testing the efficacy of an agent designed to prevent a form of liver cancer. In this case, the target organ is the liver.